Statement of
The Honorable Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
on Various Research Issues
before the
Subcommittee on Oversight and Investigations
of the
Committee on Veterans' Affairs
U.S. House of Representatives

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to appear before you to discuss various research and development issues that we understand you are interested in. Specifically, my testimony focuses on the Department of Veterans Affairs (VA) technology transfer program, non-profit research corporations and educational foundations, and human subject protections. With me today are Dr. James F. Burris, Chief Research and Development Officer; Dr. John H. Mather, Chief Officer, Office of Research Compliance and Assurance; Dr. Mindy L. Aisen, Director, Rehabilitation Research and Development Service; and Mr. John A. Bradley, Director of Finance, Office of Research and Development.

1. VA Technology Transfer Program (TTP)

The history of the VA research program is a history of discoveries that have benefited not only veterans but also all American citizens. VA researchers have played key roles in developing the cardiac pacemaker, the CAT Scanner, the Seattle Foot, magnetic resonance imaging, and the nicotine patch. The first liver transplant in the United States was performed at a VA medical facility, and VA researchers pioneered the first successful drug treatments for high blood pressure and schizophrenia.

For many years, VA did not claim ownership rights to the new technologies its researchers developed. As a result, VA facilities and laboratories lost the opportunity to benefit financially from the discoveries they brought to life. Some important VA discoveries that did not capture the interest of private industry were never offered to the general public, despite their benefits to veterans and others. Today, VA takes credit for both the past and the future work of its researchers. If that work results in financial gain, VA uses that gain on behalf of veterans.

To facilitate this vision, the TTP requires that VA assert an ownership interest whenever appropriate, so that VA can build upon its discoveries and ensure access to technologies by veterans. The TTP is committed to supporting the highest quality intramural research program. This means not only moving discovery from the laboratory to clinical practice in a timely manner, but also

assuring that inventors and their host VA medical centers (VAMC) receive optimal advice and support so that they may realize equitable compensation and recognition.

VA operates a substantial research program in connection with the research programs at many of the medical institutions with whom it is affiliated. As a result, many VA researchers also hold academic appointments with VA affiliates. Some of VA's best and most beneficial inventions have come out of this setting, and VA continues to promote this research relationship, as it benefits our veterans and the public generally.

Although VA can assert an ownership right in inventions made by its employees under Executive Order 10096, it cannot, and does not, do so to the exclusion of our university partners or the inventors. Since many of VA's researchers hold dual appointments with VA and a university, VA recognizes that, in such cases, the universities often have an interest in an invention made at a VA facility, leading to joint ownership.

To further enhance cooperation between VA and its research affiliates, and to facilitate the technology transfer process, VA's TTP developed a Cooperative Technology Administration Agreement (CTAA). The first such agreement, developed in collaboration with the University of California, was signed in May 2000 and included all 10 campuses of the University system. This CTAA served as the template for future agreements with other affiliates, but has evolved with input from other research partners. To date, over 50 percent of our major university partners have executed a CTAA with VA. In the absence of a CTAA, VA and an affiliated university would have to negotiate jointly developed technology on a case-by-case basis, a time consuming and expensive process. With a CTAA, an affiliated university will generally take the lead on patenting and commercializing jointly owned inventions.

VA understands that the Bayh-Dole Act has imposed certain requirements and responsibilities on its university research affiliates. VA believes that its own rights, responsibilities, and interests in the operation of a research program are not in conflict with those requirements.

VA has been meeting with members of the Association of American Medical Colleges and the Council on Governmental Relations to discuss VA technology transfer issues. Both organizations expressed general support of the use of the CTAA but also requested that VA consider authorizing variations from the model CTAA as circumstances at individual research universities dictate. VA has provided an updated model CTAA on the Research web site that allows potential partners to select specific language that best suits their particular needs for certain sections of the CTAA. Feedback on this has been very positive. The website also contains other information to assist partners in understanding this program.

When VA is the sole owner, or the only joint owner with a university partner that does not wish to take the lead in developing an invention, VA may choose to patent and commercialize the intellectual property. In the last two years, nine patent applications have been submitted to the US Patent and Trademark Office (USPTO) for action. An additional five applications are in

preparation with contract patent counsel for submission to USPTO. VA has recently concluded its first commercial licensing agreement and will finalize a second agreement this autumn.

VA's intellectual property portfolio has grown steadily from FY 1999 to date, as shown below.

- In FY 1999, VA received 48 invention disclosures and asserted ownership rights on 20. Of those 20 inventions, 12 involved joint ownership where the affiliate assumed the lead. In the remaining eight, VA obtained sole ownership or assumed responsibility as the lead agency. VA retained a government use license in 13 inventions.
- In FY 2000, VA received 85 invention disclosures and VA asserted ownership rights on 51. Thirty-nine (39) involved joint ownership where the affiliate assumed the lead. VA obtained sole ownership or assumed responsibility as the lead agency in the remaining 12. VA retained a government use license in 18 inventions.
- In FY 2001, VA received 132 invention disclosures and asserted ownership rights on 91. Sixty-eight involved joint ownership where the affiliate assumed the lead. In 20, VA obtained sole ownership or assumed responsibility as the lead agency. Three are being handled under public domain processing. VA retained a government use license in 15 inventions.
- In FY 2002 to date, VA has received 115 invention disclosures. VA has asserted ownership rights on 62, 55 of which involved joint ownership where the affiliate assumed the lead. VA obtained sole ownership or assumed responsibility as the lead agency in 7, and none were handled under public domain processing. VA retained a government use license in 7 inventions.

2. Non-profit Research Corporations and Educational Foundations

In 1988, Congress authorized the creation of non-profit research corporations at VAMCs to support the VA research mission. Public Law 106-117 (1999), the Veterans Millennium Health Care and Benefits Act, expanded the authority to create new VA non-profit corporations to support research or education or both. It also authorized existing VA non-profit corporations to expand their mission to include support of education activities as well as research. Education activities supported by the non-profits may be directed at patients or employees. Such activities include broad instructional learning experiences for veterans and their families that focus on improving and maintaining patient health as well as work-related instruction and training for VA staff.

There are 85 active VA non-profit research corporations and educational foundations (non-profits). These non-profits enable the Department to spend optimally the funds it receives from non-VA sources. The non-profits are not subject to Federal employment regulations or ceilings.

In 2001, non-profits received $179.5 million in donations, grants, and interest for both research and education activities. Non-profits supported almost 4,700 VA-approved projects. Many are medical research clinical trials that focus on conditions prevalent in the veteran population and thus provide a direct benefit to VA patients. Non-profits also provide salary support for clinical

research personnel to monitor veteran patients enrolled in clinical trials. These services enable the research participants to receive additional care and attention. In addition, the general public benefits from approval of new treatments that are developed through this research.

Non-profits also enable many facilities to fund essential services. For example, some non-profits, such as the McGuire Research Institute in Richmond, Virginia, are helping facilities meet increasingly complex and stringent human research requirements by hiring research compliance and institutional review board (IRB) staff. Others, such as the Atlanta Research and Education Foundation, have paid for numerous renovation and repair projects, which include the design and remodeling of laboratories. The Indiana Institute for Medical Research has purchased confocal microscopes and other equipment for the Indianapolis VAMC.

In 2001, non-profits managed funds very efficiently, as evidenced by a low administrative overhead rate whose mean and median equaled 11 percent. As a result, 90 percent of all non-profit expenditures directly supported approved research and education. This reflects the sound oversight and management of each board of directors and the dedicated efforts of the non-profit staffs.

VA assigns primary oversight of non-profits to the local facility leadership. The facility director approves all board members and, as required by statute, serves on the board with the facility chief of staff and the associate chief of staff for research/education. A certified public accountant and an external auditor assist each corporation board of directors in their oversight function. In addition, facility directors have at their disposal the same measures to prevent waste, fraud, and abuse in the operations of the VA non-profits as they do for other organizations within their purview. This would include, for example, a request that the Chief Financial Officer at the facility review certain corporation documents or investigations conducted by the Office of the Inspector General. Non-profits also are subject to audit and inspection by the Internal Revenue Service. They also receive periodic scrutiny by state, city, and other local government agencies.

3. Human Subject Protections

VA is fully committed to protecting those who participate in clinical trials and other research projects. At the previous hearing, I described many of the initiatives that VA has undertaken to ensure that its scientists and research staff fully understand and comply with the stringent ethical principles and rigorous regulatory requirements of our human research protection program. The role of the Office of Research Compliance and Assurance (ORCA) was discussed at the previous hearing. In this statement I will update information previously provided and focus more on the activities of VA's Office of Research and Development (ORD).

During the past three years VA facilities received more than $85 million to support research administrative functions including human subject protections. This funding has permitted facilities to increase staffing, education, resources (such as computers and computer software to allow better tracking and more

complete record keeping), and networking among facilities to disseminate best practices and model documents.

This year, ORD is providing over $30 million per year in administrative support funding, and it will make up to an additional $10 million in non-recurring funds available over two years for Institutional Review Board-related proposals.

An important educational tool is the Research and Development Accreditation Consultation Team, or ReDACT. ReDACT offers consultation, coaching and counseling for local IRBs and research personnel. The team consists of experts in human subjects protection and National Committee on Quality Assurance (NCQA) standards, and we expect it to be a key part of VA's effort to protect research participants.

Participants in clinical trials will also benefit from several other initiatives. ORD has collaborated with veterans service organizations to convene focus groups that review informed consent documents and procedures to make the process more understandable and meaningful to potential research participants. Trial investigators must receive formal training in human research protections before submitting research proposals to their IRB for review and approval. In addition, investigators in our Cooperative Studies Program, a program that conducts very large multi-site studies, must attend training in Good Clinical Practices, the international "gold standard" for conducting clinical trials. A Site Monitoring and Review Team (SMART) provides site monitoring and Good Clinical Practices reviews in an effort to improve the conduct of clinical trials. SMART conducts approximately 125 random and requested site visits per year. VA also ensures that the activities of research personnel comply with applicable medical privacy rules mandated by the Health Insurance Portability and Accountability Act of 1996.

The Handbook on Human Subjects Protection is awaiting final review before being disseminated to the field. The handbook combines the concerted effort of both VA and non-VA experts in the field of human subjects protection to enhance VA policies. Facilities will need virtually no additional time and effort to implement the handbook. The draft handbook has been available on VA's web site throughout its development and many of the new requirements are good clinical practices that the field has begun to adopt. ORD is also developing a Web-based instruction/guidance document on writing informed consent documents. Educational efforts will also be provided through national and regional conferences, programs in conjunction with the ReDACT effort, and national conference calls.

Indicative of the success of these efforts is a recent quality improvement survey that ORD conducted. Ninety-seven percent of responding research subjects agreed with the statement "The Informed Consent process including discussion with study staff gave me the information needed to make an informed decision about whether or not to participate in the study."

At the previous hearing, I discussed at length VA's efforts to accredit its human research protection programs through the National Committee on Quality Assurance (NCQA). As of September 18, 2002, eight additional final reports have been issued, with seven facilities being "Accredited with Conditions," and

one site receiving “Not Accredited” status. Cumulatively, 15 facilities have been "Accredited with Conditions," two have received a final result of "Not Accredited," two have received a preliminary result of “Not Accredited,” and four sites still await final reports. ORCA is continuing to conduct reviews at these sites.

I also noted that this first-of-its-kind program had temporarily suspended accreditation reviews in order to conduct quality improvement activities, based on the experiences of the first 23 inspections. VA and NCQA have both agreed that the standards needed modification to help streamline the review process and to clarify selected requirements. As a result, NCQA released revised standards for public comment on September 5.

The revised standards reflect Institute of Medicine recommendations encouraging institutions to involve participants in human research programs. NCQA has proposed broadening standards requiring research centers to conduct surveys of participants and potential participants and to use their input to help improve their research and their human subject protection programs. The standards also promote self-evaluation, through which VA medical centers can analyze and rate their own performance, and continuously improve their research programs.

For the program’s second year, NCQA and VA have agreed on an approach to coordinate oversight requirements for VAMCs that use the IRBs of affiliated academic institutions. Under this process, sites that use the IRBs of an academic affiliate accredited by another IRB accounting body, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), will be permitted to undergo a more limited NCQA survey. Upon completion of the survey, NCQA will issue an accreditation decision that combines the results of the NCQA and AAHRPP surveys. NCQA, AAHRPP, and VA will be developing detailed plans to implement the new process in the coming weeks.

Mr. Chairman, this concludes my statement. My colleagues and I will now be happy to answer any questions that you and other members of the Subcommittee might have.